K082918

Medtronic Sofamor Danek
MASTERGRAFT® Resorbable Ceramic Granules
510(K) Summary
September 2008

FEB - 9 2009

I. **Company:** **Medtronic Sofamor Danek USA**
1800 Pyramid Place
Memphis, TN 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: **Ryan Massey**
Regulatory Affairs Specialist

II.Proposed Proprietary Trade Name:	MASTERGRAFT Resorbable Ceramic Granules
Classification Name:	Resorbable calcium salt bone void filler
Product Code:	MQV
Regulation No.:	888.3045

III. Product Description/Purpose of Application

MASTERGRAFT® Resorbable Ceramic Granules is made of medical grade combination of hydroxyapatite and b-tricalcium phosphate. MASTERGRAFT® is provided in a 60 percent hydroxyapatite and 40 percent b-tricalcium phosphate formulation. Alternatively, MASTERGRAFT® may be provided in a 15 percent hydroxyapatite and 85 percent b-tricalcium phosphate formulation. The product is supplied sterile for single patient use. MASTERGRAFT® Resorbable Ceramic Granules is an osteoconductive porous implant.

The purpose of this 510(k) application is to expand the indications for the MASTERGRAFT® Resorbable Ceramic Granules device so that it may be used with autograft as a bone graft extender, as well as expand the size range to include smaller sizes. Like the previously cleared predicates, MASTERGRAFT® Resorbable Ceramic Granules (K020986, SE 07/22/2002) and MBCP™ (K051774, SE 01/20/2006), the subject system is intended as a bone void filler for bony voids or gaps that are not intrinsic to the stability

of the bony structure. In addition, MASTERGRAFT® Resorbable Ceramic Granules can be mixed with autograft and used as a bone graft extender.

IV. Indications

MASTERGRAFT® Resorbable Ceramic Granules is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Additionally, MASTERGRAFT® Resorbable Ceramic Granules can be used with autograft as a bone graft extender. MASTERGRAFT® Resorbable Ceramic Granules is to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, pelvis, ilium and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MASTERGRAFT® Resorbable Ceramic Granules provides a bone void filler that resorbs and is replaced with bone during the healing process.

V. Substantial Equivalence

Documentation is provided that demonstrates MASTERGRAFT® Resorbable Ceramic Granules to be substantially equivalent to the previously cleared MASTERGRAFT® Resorbable Ceramic Granules (K020986, SE 07/22/2002) and MBCP™ (K051774, SE 01/20/2006).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Sofamor Danek USA, Inc.
% Mr. Ryan Massey
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

FEB - 9 2009

Re: K082918
Trade/Device Name: MASTERGRAFT® Resorbable Ceramic Granules
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: January 22, 2009
Received: February 3, 2009

Dear Mr. Massey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: MASTERGRAFT® Resorbable Ceramic Granules

Indications for Use:
MASTERGRAFT® Resorbable Ceramic Granules is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Additionally, MASTERGRAFT® Resorbable Ceramic Granules can be used with autograft as a bone graft extender. MASTERGRAFT® Resorbable Ceramic Granules is to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, pelvis, ilium and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MASTERGRAFT® provides a bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use __X___ Per 21 CFR 801.109 OR Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082918